



NEWS RELEASE

Lantern Pharma Receives Regulatory Approval to Expand Harmonic™ Clinical Trial for Non-Small Cell Lung Cancer in Never-Smokers into Japan and Taiwan

2024-04-22

- Approximately 33% of all non-small cell lung cancer patients in East Asia are never smokers – a growing and unaddressed patient population.
- Dr. Yashushi Goto a leading lung cancer clinician-scientist at the renowned National Cancer Center of Japan will be a lead investigator.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence ("AI") company developing targeted and transformative cancer therapies using its proprietary RADR® AI and machine learning ("ML") platform with multiple clinical-stage drug programs, announced today that – the company has received regulatory approval to expand its **Harmonic™ trial**, a Phase 2 clinical study evaluating LP-300 in non-small cell lung cancer (NSCLC) in never-smokers in both Japan and Taiwan. Approximately one third of all lung cancer patients in East Asia are never-smokers and the proportion of lung cancer in never smokers (LCINS) has been increasing gradually over time, according to a publication in **Translational Lung Cancer Research** ⁽¹⁾.

The approval to proceed with the Phase 2 clinical trials in Japan and Taiwan are expected to accelerate the collection of patient and response data needed for the next-stage of evaluation and development of LP-300, a therapeutic for the treatment of relapsed and inoperable primary adenocarcinoma of the lung given in combination with chemotherapy. Additionally, it may also bring a needed therapeutic option for LCINS diagnosed patients in Japan and Taiwan, where one-third of all lung cancer diagnoses are made among those who have never smoked.

Finally, Lantern believes that this improves the positioning for drug-candidate LP-300 to develop collaborative and co-development partnerships with global biopharma companies with a primary focus in serving the Asian markets.

LCINS are histologically, mutationally, and epidemiologically distinct from smoking-related lung cancers and occur almost exclusively as adenocarcinomas and most commonly in women and individuals of Asian ancestry.⁽²⁾ LCINS are highly enriched for alterations in the tyrosine kinase (TK) genes, have low tumor mutation burden (TMB) and low rates of PD-L1 expression.⁽²⁾ Many of these factors may provide clarity on why LP-300 seems to have a distinct mechanism of action and anti-cancer activity in tumors among LCINS patients. Lantern believes that this unique mechanism of action and historically observed anti-tumor activity may ultimately prove to be a useful option for this growing class of patients globally.

Dr. Yashushi Goto, a physician and researcher focused on lung cancer at the **National Cancer Center of Japan**, has been watching the development of LP-300 and the Harmonic™ trial in the United States with interest. Dr. Goto will now lead the trial in Japan, where the incidence of non-small cell lung cancer (NSCLC) in never-smokers is double or more than that of the United States. Dr. Goto stated, "LP-300 represents a promising new treatment option for never-smokers with advanced NSCLC harboring driver mutations like EGFR, ALK, ROS1, and MET, who have limited choices after progressing on targeted therapies. The Harmonic trial brings renewed hope to those facing this devastating disease, especially in East Asia, where EGFR mutations are highly prevalent. I am deeply gratified to contribute to the development of this innovative therapy that could potentially transform the treatment landscape for never-smokers battling advanced lung cancer."

The Harmonic™ trial (**NCT05456256**) is a Phase 2 clinical trial that is assessing the effect of Lantern's investigational new drug LP-300 in combination with standard-of-care (SOC) chemotherapy, pemetrexed and carboplatin, on the overall and progression-free survival of never smoker patients with advanced NSCLC. The study has been designed as a 90 patient trial with approximately 2/3rds (60) of the patients receiving LP-300 with a chemotherapy doublet and the remaining 1/3rd (30) receiving the standard of care chemotherapy doublet alone. In a previous multi-center Phase 3 clinical trial, a subset of never smoker NSCLC patients who received LP-300 with chemotherapy showed increased overall and two-year survival of 91% and 125%, respectively, compared to patients who only received chemotherapy. In addition, LP-300 has been administered in multiple clinical trials to more than 1,000 people and has been generally well tolerated. Additional information on the Harmonic™ trial can be found at the **Harmonic™ clinical trial website**, on **ClinicalTrials.gov**, or on the first-of-its-kind **Harmonic™ trial iPhone app**, which is focused on education & awareness for never smoker NSCLC patients and the NSCLC community.

References:

Zhou F, Zhou C. Lung cancer in never smokers-the East Asian experience. *Transl Lung Cancer Res*. 2018

Aug;7(4):450-463. <https://doi.org/10.21037/tlcr.2018.05.14>. PMID: 30225210; PMCID: PMC6131183

LoPiccolo, J., Gusev, A., Christiani, D.C. et al. Lung cancer in patients who have never smoked — an emerging disease. *Nat Rev Clin Oncol* **21**, 121–146 (2024). <https://doi.org/10.1038/s41571-023-00844-0>

About Lung Cancer in Never Smokers:

NSCLC presents differently in never smokers, which are defined by the CDC as a person who has smoked 100 cigarettes or less in their life, compared to smokers. These differences are believed to be due to a higher percentage of genetic mutations in a family of cancer-promoting genes called Tyrosine Kinases (TK). Changes in TK genes, such as EGFR, ALK, ROS and MET, can contribute to the development of healthy cells into cancer cells, leading to tumor formation and growth. LP-300's intended mechanism is to work together with chemotherapy by strongly interacting in the TK gene pathways, interrupting their activity to slow or prevent tumor growth and spread.

According to the American Cancer Society, lung cancer is the second leading cause of cancer in the US, with over 200,000 patients diagnosed annually. Historically, never smokers with NSCLC make up about 15-20% of all lung cancer patients, representing an approximate annual market potential of \$1.5 to \$2.0 billion.

About Lantern Pharma:

Lantern Pharma (NASDAQ: LTRN) is an AI company transforming the cost, pace, and timeline of oncology drug discovery and development. Our proprietary AI and machine learning (ML) platform, RADR[®], leverages over 60 billion oncology-focused data points and a library of 200+ advanced ML algorithms to help solve billion-dollar, real-world problems in oncology drug development. By harnessing the power of AI and with input from world-class scientific advisors and collaborators, we have accelerated the development of our growing pipeline of therapies that span multiple cancer indications, including both solid tumors and blood cancers and an antibody-drug conjugate (ADC) program. On average, our newly developed drug programs have been advanced from initial AI insights to first-in-human clinical trials in 2-3 years and at approximately \$1.0 - 2.5 million per program.

Our lead development programs include a Phase 2 clinical program and multiple Phase 1 clinical trials. We have also established a wholly-owned subsidiary, Starlight Therapeutics, to focus exclusively on the clinical execution of our promising therapies for CNS and brain cancers, many of which have no effective treatment options. Our AI-driven pipeline of innovative product candidates is estimated to have a combined annual market potential of over \$15 billion USD and have the potential to provide life-changing therapies to hundreds of thousands of cancer patients across the world.

Please find more information at:

- Website: www.lanternpharma.com
- LinkedIn: <https://www.linkedin.com/company/lanternpharma/>
- X: [@lanternpharma](https://twitter.com/lanternpharma)

Forward-looking Statements:

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, among other things, statements relating to: future events or our future financial performance; the potential advantages of our RADR[®] platform in identifying drug candidates and patient populations that are likely to respond to a drug candidate; our strategic plans to advance the development of our drug candidates and antibody drug conjugate (ADC) development program; estimates regarding the development timing for our drug candidates and ADC development program; expectations and estimates regarding clinical trial timing and patient enrollment; our research and development efforts of our internal drug discovery programs and the utilization of our RADR[®] platform to streamline the drug development process; our intention to leverage artificial intelligence, machine learning and genomic data to streamline and transform the pace, risk and cost of oncology drug discovery and development and to identify patient populations that would likely respond to a drug candidate; estimates regarding patient populations, potential markets and potential market sizes; sales estimates for our drug candidates and our plans to discover and develop drug candidates and to maximize their commercial potential by advancing such drug candidates ourselves or in collaboration with others. Any statements that are not statements of historical fact (including, without limitation, statements that use words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "model," "objective," "aim," "upcoming," "should," "will," "would," or the negative of these words or other similar expressions) should be considered forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by the forward-looking statements, such as (i) the risk that our research and the research of our collaborators may not be successful, (ii) the risk that promising observations in preclinical studies do not ensure that later studies and development will be successful, (iii) the risk that we may not be successful in licensing potential ADC candidates or in completing potential partnerships and collaborations, (iv) the risk that none of our product candidates has received FDA marketing approval, and we may not be able to successfully initiate, conduct, or conclude clinical testing for or obtain marketing approval for our product candidates, (v) the risk that no drug product based on our proprietary RADR[®] AI platform has received FDA marketing approval or otherwise been incorporated into a commercial product, and (vi) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on March 18, 2024. You may access our

Annual Report on Form 10-K for the year ended December 31, 2023 under the investor SEC filings tab of our website at www.lanternpharma.com or on the SEC's website at www.sec.gov. Given these risks and uncertainties, we can give no assurances that our forward-looking statements will prove to be accurate, or that any other results or events projected or contemplated by our forward-looking statements will in fact occur, and we caution investors not to place undue reliance on these statements. All forward-looking statements in this presentation represent our judgment as of the date hereof, and, except as otherwise required by law, we disclaim any obligation to update any forward-looking statements to conform the statement to actual results or changes in our expectations.

Lantern Pharma Disclosure Channels to Disseminate Information:

Lantern Pharma's investors and others should note that we announce material information to the public about our company and its technologies, clinical developments, licensing matters and other matters through a variety of means, including Lantern Pharma's website, press releases, SEC filings, digital newsletters, and social media, in order to achieve broad, non-exclusionary distribution of information to the public. We encourage our investors and others to review the information we make public in the locations above as such information could be deemed to be material information. Please note that this list may be updated from time to time.

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Source: Lantern Pharma Inc.

Released April 22, 2024